REMARKS

Claims 1-13 are pending. Applicant has amended claims 1, 11, and 12, to provide greater clarity. Support for the amendment is found at page 9, lines 11-15. Accordingly, this amendment does not introduce any new matter.

Rejection Under 35 U.S.C. § 112, Second Paragraph

Claims 1-13 are rejected under 35 U.S.C. § 112, second paragraph.

The Office Action alleges that claim 1 is incomplete for omitting an essential step of relating the anti-inflammatory compound recited in the preamble with the observation of a decrease in the incidence of infarctions. Applicant respectfully traverses. Claim 1 recites a comparing step which compares incidence of infarctions in the subject patient group with that in a control sample of patients. Claim 1 further recites that "a decrease in the incidence of infarctions in the subject group indicates effectiveness of the compound." Thus, claim 1 already includes correlating the effectiveness of the anti-inflammatory compound with a decrease in the incidence of infarctions and does not omit any essential steps.

The Office Action further alleges that claim 1 is unclear as to whether the measurement of a peak level of CK-MB takes place before or after the procedure involving cardiopulmonary bypass. Applicant has amended claim 1 to recite "the peak level of CK-MB is measured during and/or after the procedure involving cardiopulmonary bypass." Support for this is found at page 9, lines 11-12, where it is stated that measurements were made on "intra- and post-operative blood draws." Therefore, claim 1 as amended is clear and unambiguous.

The Office Action also states that claim 11 recites "the antibody" without antecedent basis. Applicant has amended claim 11 in connection with the antecedent basis issue.

Accordingly, reconsideration and withdrawal of these rejections are respectfully requested.

Rejection Under 35 U.S.C. § 102(b)

Claims 1-13 are rejected under 35 U.S.C. § 102(b) as being anticipated by Fitch et al. Specifically, the Office Action states that the pending claims are drawn to a method of determining the effectiveness of an anti-inflammatory compound in a patient undergoing a procedure involving cardiopulmonary bypass (CPB) and comparing incidence of infarctions with control subjects wherein both groups have a blood level of creatine kinase (as CK-MB) of at least a certain level in ng/ml, and alleges that the claimed methods are not different in practice from the method taught by Fitch et al. Applicant respectfully traverses this rejection.

Fitch et al. teach that a single-chain antibody specific for human C5 is effective against pathological complement activation in patients undergoing CPB and that postoperative myocardial injury can be determined by measuring the cumulative release of CK-MB over 24 hours. In particular, Figure 4 in Fitch et al. shows the measurement of the cumulative release of CK-MB over 24 hours as represented by CK-MB AUC (area under the curve). However, Fitch et al. do not teach measuring the postoperative **peak** level of CK-MB or suggest any significance of the peak level of CK-MB as opposed to the cumulative level or AUC of CK-MB. Applicant respectfully submits that the peak level and AUC are two distinct pharmacokinetic parameters and a measurement of AUC is different from a measurement of the peak level. Accordingly, Fitch et al. do not teach or suggest measuring the peak level of CK-MB as required by the pending claims. Thus, the pending claims are patentable over Fitch et al., and reconsideration and withdrawal of this rejection are respectfully requested.

CONCLUSION

In view of the foregoing amendments and remarks, Applicant submits that the pending claims are in condition for allowance. Early and favorable reconsideration is respectfully solicited. The Examiner may address any questions raised by this submission to the undersigned at 617-951-7000. Please charge any fees or credit any overpayments to our Deposit Account No. 18-1945 from which the undersigned is authorized to draw, under order no. ALXN-P02-059.

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Respectfully submitted,

By _____

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